Summary of Community decisions on marketing authorizations in respect of medicinal products from 1 December 2007 to 31 December 2007

(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]))

(2008/C 19/04)

— Issuing of a marketing authorization (Article 13 of Regulation (EC) No 726/2004): Accepted

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
11.12.2007	NEVANAC	Nepafenac	Alcon Laboratories (UK) Ltd Boundary Way Hemel Hempstead Herts HP2 7UD United Kingdom	EU/1/07/433/001	Eye drops, suspension	S01BC10	13.12.2007
11.12.2007	Pioglitazone/ metformin hydrochloride Takeda	Pioglitazone/metformin hydrochloride	Takeda Global Research and Development Centre (Europe) Ltd Arundel Great Court 2 Arundel Street London WC2R 3DA United Kingdom	EU/1/07/421/001-009	Film-coated tablet	A10BD05	13.12.2007
12.12.2007	Olanzapine Teva	Olanzapine	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht Nederland	EU/1/07/427/001-022 EU/1/07/427023-037	Film-coated tablet Orodispersible tablets	N05AH03	14.12.2008
13.12.2007	Atripla	Efavirenz/emtricitabine/ tenofovir disoproxil fumarate	Bristol-Myers Squibb Gilead Sciences And Merck Sharp & Dohme Limited Unit 13 Stillorgan Industrial Park Blackrock, Co.Dublin Ireland	EU/1/07/430/001	Film-coated tablet	J05AR06	18.12.2008
18.12.2007	Retacrit	Epoetin zeta	HOSPIRA Enterprises B.V. Taurusavenue 19-21b 2132 LS Hoofddorp Nederland	EU/1/07/431/001-019	Solution for injection	B03XA01	20.12.2007

([1]) OJ L 136, 30.4.2004, p. 1.

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18.12.2007	Silapo	Epoetin zeta	STADA Arzneimittel AG Stadastraße 2-18 D-61118 Bad Vilbel	EU/1/07/432/001-019	Solution for injection	B03XA01	20.12.2007
20.12.2007	ISENTRESS	Raltegravir	Merck Sharp & Dohme Limited Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/07/436/001-002	Film-coated tablets	J05AX08	2.1.2008

— **Modification of a marketing authorization (Article 13 of Regulation (EC) No 726/2004): Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
11.12.2007	RotaTeq	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk F-69007 Lyon	EU/1/06/348/001-002	13.12.2007
11.12.2007	TARGRETIN	Eisai Limited 3, Shortlands London W6 8EE United Kingdom	EU/1/01/178/001	13.12.2007
11.12.2007	Quintanrix	GlaxoSmithKline Biologicals s.a. rue de l'Institut 89 B-1330 Rixensart	EU/1/04/301/001-005	13.12.2007
11.12.2007	Tandemact	Takeda Global Research and Development Centre (Europe) Ltd Arundel Great Court 2 Arundel Street London WC2R 3DA United Kingdom	EU/1/06/366/005-016	13.12.2007
11.12.2007	Procomvax	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk F-69007 Lyon	EU/1/99/104/001	13.12.2007
11.12.2007	Prevenar	Wyeth-Lederle Vaccines S.A. Rue du Bosquet 15 B-1348 Louvain-La-Neuve	EU/1/00/167/001-007	13.12.2007

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12.12.2007	Quadramet	CIS bio international Boite Postale 32 F-91192 Gif-sur-Yvette	EU/1/97/057/001	14.12.2007
12.12.2007	Sonata	Meda AB Pipers väg 2A S-170 09 Solna Wyeth Europa Limited Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH United Kingdom	EU/1/99/102/001-008	17.12.2007 14.12.2007
14.12.2007	Avastin	Roche Registration Limited 6 Falcon Way Shire Park Welwyn Garden City AL7 1TW United Kingdom	EU/1/04/300/001-002	18.12.2007
14.12.2007	Ariclaim	Eli Lilly Nederland B.V. Grootslag 1-5 3991 RA Houten Nederland	EU/1/04/283/008-012	18.12.2007
14.12.2007	Caelyx	Schering Plough Europe Rue de Stalle, 73 B-1180 Bruxelles Stallestraat, 73 B-1180 Brussel	EU/1/96/011/001-004	18.12.2007
14.12.2007	Diacomit	Biocodex 7, avenue Gallieni F-94250 Gentilly	EU/1/06/367/001-012	18.12.2007
14.12.2007	RotaTeq	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk F-69007 Lyon	EU/1/06/348/001-002	18.12.2007
14.12.2007	Rebif	Serono Europe Limited 56, Marsh Wall London E14 9TP United Kingdom	EU/1/98/063/001-007	18.12.2007

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14.12.2007	Velcade	Janssen-Cilag International NV Turnhoutseweg, 30 B-2340 Beerse	EU/1/04/274/001	18.12.2007
18.12.2007	Tracleer	Actelion Registration Ltd BSI Building 13th Floor 389 Chiswick High Road London W4 4AL United Kingdom	EU/1/02/220/001-005	20.12.2007
18.12.2007	Xelevia	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/07/382/001-018	20.12.2007
18.12.2007	Infanrix Penta	GlaxoSmithKline Biologicals s.a. rue de l'Institut 89 B-1330 Rixensart	EU/1/00/153/001-010	20.12.2007
18.12.2007	Lyrica	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/1/04/279/001-043	21.12.2007
18.12.2007	Prezista	Janssen-Cilag International NV Turnhoutseweg, 30 B-2340 Beerse	EU/1/06/380/001	20.12.2007
18.12.2007	Betaferon	Bayer Schering Pharma AG Müllerstraße 170-178 D-13342 Berlin	EU/1/95/003/003-006	20.12.2007
18.12.2007	Helixate NexGen	Bayer HealthCare AG D-51368 Leverkusen	EU/1/00/144/004	20.12.2007
18.12.2007	KOGENATE Bayer	Bayer HealthCare AG D-51368 Leverkusen	EU/1/00/143/010-011	20.12.2007
18.12.2007	Zonegran	Eisai Limited 3, Shortlands London W6 8EE United Kingdom	EU/1/04/307/001-013	20.12.2007

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18.12.2007	NovoMix	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd	EU/1/00/142/004-005 EU/1/00/142/009-010	20.12.2007
18.12.2007	Insuman	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main	EU/1/97/030/028-109 EU/1/97/030/085-139	20.12.2007
18.12.2007	Truvada	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/04/305/001	20.12.2007
19.12.2007	CUBICIN	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/05/328/001-002	21.12.2007
19.12.2007	Humira	Abbott Laboratories Ltd Queenborough Kent ME11 5EL United Kingdom	EU/1/03/256/001-010	21.12.2007
19.12.2007	Tygacil	Wyeth Europa Ltd Huntercombe Lane South Taplow Maidenhead Berkshire SL6 0PH United Kingdom	EU/1/06/336/001	21.12.2007
19.12.2007	MabCampath	Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden Nederland	EU/1/01/193/001-002	21.12.2007
19.12.2007	Lucentis	Novartis Europharm Limited Wimblehurst Road Horsham West Sussex RH12 5AB United Kingdom	EU/1/06/374/001	21.12.2007
19.12.2007	REYATAZ	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park Sanderson Road Uxbridge UD8 1DH United Kingdom	EU/1/03/267/001-007	21.12.2007

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19.12.2007	Januvia	Merck Sharp & Dohme Ltd Hertford Road Hoddesdon Hertfordshire EN11 9BU United Kingdom	EU/1/07/383/001-018	21.12.2007
19.12.2007	Aptivus	Boehringer Ingelheim International GmbH Binger Straße 173 D-55216 Ingelheim am Rhein	EU/1/05/315/001	21.12.2007
20.12.2007	Infanrix Hexa	GlaxoSmithKline Biologicals s.a. rue de l'Institut 89 B-1330 Rixensart	EU/1/00/152/001-018	24.12.2007
20.12.2007	Aldurazyme	Genzyme Europe B.V. Gooimeer 10 1411 DD Naarden Nederland	EU/1/03/253/001-003	24.12.2007
20.12.2007	Insulin Human Winthrop	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main	EU/1/06/368/001-087	27.12.2007
21.12.2007	Remicade	Centocor B.V. Einsteinweg 101 2333 CB Leiden Nederland	EU/1/99/116/001-003	27.12.2007
21.12.2007	Keppra	UCB Pharma SA. Allée de la Recherche 60 B-1070 Bruxelles Researchdreef, 60 B-1070 Brussel	EU/1/00/146/001-030	26.12.2007
21.12.2007	Mimpara	Amgen Europe B.V. Minervum 7061 4817 ZK Breda Nederland	EU/1/04/292/001-012	27.12.2007
21.12.2007	Macugen	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/1/05/325/002	2.1.2008

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21.12.2007	Somavert	Pfizer Ltd Ramsgate Road Sandwich Kent CT 13 9NJ United Kingdom	EU/1/02/240/001-004	27.12.2007
21.12.2007	Parareg	Dompé Biotec S.p.A. Via San Martino, 12 I-20122 Milano	EU/1/04/293/001-012	2.1.2008
21.12.2007	GONAL-F	Serono Europe Limited 56, Marsh Wall London E14 9TP United Kingdom	EU/1/95/001/001 EU/1/95/001/003-005 EU/1/95/001/009 EU/1/95/001/012 EU/1/95/001/021-022 EU/1/95/001/025-028 EU/1/95/001/031-035	2.1.2008
21.12.2007	HBVAXPRO	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk F-69007 Lyon	EU/1/01/183/001 EU/1/01/183/004-005 EU/1/01/183/007-008 EU/1/01/183/011 EU/1/01/183/013 EU/1/01/183/015 EU/1/01/183/018-029	26.12.2007

— **Withdrawal of a marketing authorization (Article 13 of Regulation (EC) No 726/2004)**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
18.12.2007	Levviax	Aventis Pharma S.A 20, avenue Raymond Aron F-92165 Antony Cedex	EU/1/01/192/001-005	20.12.2007

— **Modification of a marketing authorization (Article 38 of Regulation (EC) No 726/2004): Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
14.12.2007	Suprelorin	Cyton Biosciences Ltd Hyland Mews 21 High Street Clifton Bristol BS8 2YF United Kingdom VIRBAC S.A. 1ère Avenue 2065 m L.I.D F-06516 Carros	EU/2/07/072/001-002	18.12.2007
19.12.2007	Aivlosin	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	EU/2/04/044/001-006	21.12.2007

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

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